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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------|-------------|----------------------|---------------------|------------------|
| 10/603,501 | 06/24/2003 | Nicholas Franano | 55225 CON (47703) | 3974 |
| 21874 | 7590 | 03/31/2005 | EXAMINER | |
| EDWARDS & ANGELL, LLP | | | AFREMOVA, VERA | |
| P.O. BOX 55874 | | | ART UNIT | |
| BOSTON, MA 02205 | | | PAPER NUMBER | |
| | | | 1651 | |

DATE MAILED: 03/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/603,501

Applicant(s)

FRANANO, NICHOLAS

Examiner

Vera Afremova

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-39 are pending and subject to restriction/election requirement.

Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11 and 13-18, drawn to a method for *in vitro* treating a biological conduit with an agent that can degrade extracellular matrix, classified in class 435, subclass 1.2, for example.
- II. Claims 19-24, drawn to a kit comprising an agent that can degrade extracellular matrix and a delivery device, classified in class 435, subclass 810, for example.
- III. Claims 12, 25-33 and 35, drawn to a method for *in vivo* treating a mammal suffering from or susceptible to a disorder associated with obstruction of biological conduit, classified in class 424, subclass 94.1, for example.
- IV. Claims 34 and 36-39, drawn to a method for *in vivo* treating a mammal suffering from or susceptible to biliary stricture, stenosis of hemodialysis graft, intimal hyperplasia or coronary obstruction, classified in class 424, subclass 94.1, for example.

The inventions are distinct, each from the other because of the following reasons:

Invention II and Inventions I, III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed such as composition

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comprising an agent that can degrade extracellular matrix and a delivery vehicle can be used in a materially different process. For example: US 6,074,664 discloses a composition with collagenase and a delivery vehicle for wound treatment (abstract).

Invention I and Inventions III and IV are distinct because they are directed to different methods as claimed wherein the methods encompass two distinct system of administration such as *in vitro* treatment of a biological conduit (group I) and *in vivo* treatment of mammal biological conduit (groups II and IV). The method of groups III and IV require active step of administering product to a mammal that is not required by the method of group I as claimed.

The methods of groups III and IV are distinct because they are directed to different methods as claimed wherein the patients of group IV such as patients suffering from suffering from or susceptible to biliary stricture, stenosis of hemodialysis graft, intimal hyperplasia or coronary obstruction are not required in the method of group III.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for one group is not required for the other group, restriction for examination purposes as indicated is proper.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of 1 group of 4 groups inventions listed above in order to be examined even though the requirement be traversed (37 CFR 1.143).

Election of species

This application contains claims 34 and 36-39 that are directed to the following patentably distinct species of the claimed invention: patients suffering from or susceptible to biliary stricture (1), stenosis of hemodialysis graft (2), intimal hyperplasia (3) or coronary obstruction (4).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 34 and 36 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

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the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

If Group IV (claims 34 and 36-39) is elected in reply to this office action; Applicant is advised that the reply to this requirement to be complete must include an election of one of four species listed above in order to be examined even though the requirement be traversed (37 CFR 1.143).

Claim Objections

Claims 6-12, 17, 18, 23, 24 and 29-35 are objected to under 37 CFR 1.75(c) as being in improper form because they are multiple dependent claims. See MPEP § 608.01(n).

Accordingly, these claims might not be further treated on the merits in the instant office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

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The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

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March 22, 2005

A handwritten signature in black ink, appearing to read 'V. Afremova', with a long horizontal flourish extending to the right.

VERA AFREMOVA

PRIMARY EXAMINER